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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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EXAMINER
MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/879,216	Applicant(s) RICHARD, ROBERT E.
	Examiner Jennifer Kolb Michener	Art Unit 1762

-- The MAILING DATE of this communication appears on th cover sheet with th corr spond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: In Figure 4, Examiner is unable to find reference in the specification to the reference sign "48". A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In order to overcome the new matter rejection of amended claim language directed to "non-polymeric" medical device, Applicant has amended the claim to recite "metallic medical device".

The newly-added phrase "metallic medical device" appears to be new matter. Examiner is unable to find, in the originally filed disclosure, basis for this limitation. There is no basis in the specification for claiming all metallic medical devices. The specification clearly teaches coating "stents, balloon catheters, vena-cava filters, aneurysm coils, stent-grafts, a-v shunts, angio-catheters, and PICC's" (page 9) "or any other implantable medical device" (page 4). While stents and coils *may* be made from metals, there does not appear to be basis for claiming all metal medical devices. Claimed phrase "metallic medical device" would be inclusive of, for example, a scalpel, for which Applicant's specification has no basis. Additionally, Applicant's disclosed list of suitable medical devices are not limited to being made from metals. For example, catheters are often made of polymers and stents may be made from polymers.

New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific species of a broader original disclosure.

Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.

Examiner's Suggestions/Interpretations

3. The requirement for a "metallic" medical device occurs only in the preamble of the independent claims. However, Examiner interprets the body of the claims, which refer back to "*the* medical device" (emphasis added), to require the medical device substrate to be metallic.

4. Examiner notes that claim 12 does not require a specific order to the four recited method steps. For example, the claim as written allows the medical device to be placed in the coating chamber after "coating", but before "exposing". Or the device may be placed in the coating chamber for the first coating only and then removed. Likewise, the "exposing" step does not require exposing the coating to the supercritical fluid *with* the therapeutic agent therein. Additionally, as written, the "coating" step may occur as a result of or simultaneously with the "exposing" step, wherein only one substance is coated. In the exposing step, Examiner notes that there is no active requirement for coating the medical device with therapeutic agent. As written, this "method of coating" is open to coating only with the coating of line 3, with the exposure to the supercritical fluid yielding, for example, only a swollen or sterilized coating, but not a deposition of the therapeutic agent.

When read in light of the specification, Examiner has interpreted this claim to require only the "exposing" step to occur in the coating chamber since supercritical temperatures and/or pressures are required. The "coating" step has been interpreted to require deposition of the disclosed carrier coating either prior to or simultaneously with

the exposure of the therapeutic agent in supercritical fluid. When the coating step occurs simultaneously, it is interpreted to occur within the coating chamber. When the "coating" step occurs prior to the "exposing" step, the claim has been interpreted to be open to pre-"coating" occurring either inside or outside of the coating chamber. While not required by the claim as written, the "exposing" step has been interpreted in light of the specification to require exposure of the medical device to the supercritical fluid with therapeutic therein.

Therefore, for clarity, Examiner makes the following suggestions:
If Applicant wishes to limit the entire process to occurring within the coating chamber, Examiner suggests claiming "first placing the medical device in a coating chamber". Any subsequent steps Applicant wishes to occur in a specific order should then be preceded by "and then" or the like.
Additionally, to make clear that the "coating" step of line 3 is different than any treatment with therapeutic agent, Examiner suggests Applicant use "carrier coating" language.
Finally, Examiner suggests the following language to enhance clarity of the "exposing" step: "exposing the carrier coating to the supercritical fluid, with the therapeutic therein, to transfer the therapeutic from the supercritical fluid to the medical device."

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (6,153,252) in view of Subramaniam et al. (5,833,891).

Hossainy et al. teach a method of coating metallic medical devices, such as stents (abstract; col. 3, line 11) with a polymer and a therapeutic agent (col. 1, lines 26; col. 6, line 48; col. 8, lines 36-40). Preferably the polymer and therapeutic are in solution with a solvent, however Hossainy teaches that the polymer and therapeutic may form a dispersion in the solvent, so long as care is taken to ensure that the particle size of the dispersed pharmaceutical agent particles is small enough not to cause an irregular coating surface or clog the stent slots and that the therapeutic is encapsulated by the polymer coating.

What Hossainy fails to teach is the use of supercritical fluid to deposit the therapeutic agent. It would have been obvious to one of ordinary skill in the art to look to the prior art for methods of safely coating therapeutic agents onto non-porous, inorganic substrates to create a coating with very small particles of therapeutic agent to ensure uniform coating, while avoiding degradation of the therapeutic agent.

Subramaniam is cited for teaching methods of coating therapeutic agents in a fluid dispersion onto core substrates such that very small particles are precipitated (abstract). Subramaniam uses supercritical fluid coating techniques to deposit small particles of

drugs or polymers or both (col. 2, line 29) onto core substrates in a coating chamber (col. 1, lines 34-36).

The therapeutic of Subramaniam is interfaced with supercritical fluid (col. 7, line 40), which precipitates the drug or polymer or both onto the substrate. The core particle may be glass (col. 7, line 12).

Since Hossainy teaches coating inorganic, non-porous metal medical devices with a dispersion or solution of polymer and therapeutic agent, with the desire to keep the particle size of the therapeutic agent very small, and Subramaniam teaches interfacing such a solution with supercritical fluid to deposit finely particulate therapeutic agents onto inorganic, non-porous substrates, Subramaniam would have reasonably suggested the use of supercritical fluid in the method of Hossainy. It would have been obvious to one of ordinary skill in the art to use the teachings of Subramaniam in the method of Hossainy to provide Hossainy with the small particle size of pharmaceutical agent required to create a uniform coating surface and prevent the clogging of stent slots without damaging the delicate therapeutic agents.

Examiner recognizes that the substrate of Hossainy is metal, whereas the substrate of Subramaniam is glass, however, both are non-porous, inorganic substrates to which it is shown that polymer encapsulated therapeutics adhere in a physical manner. The method of Subramaniam is cited to show that supercritical fluid is non-damaging to therapeutic agents and can be used to provide a surface coating to non-porous, inorganic substrates.

The polymer portion of Hossainy and Subramaniam's dispersion acts as the "carrier coating" of claims 2 and 8 and the "coating" of claim 12.

Subramaniam teaches spraying a stream of supercritical fluid at the substrates, as required by claims 3 and 13 (col. 6, line 50).

Regarding claim 4, in Hossainy's examples, spraying and dipping are used interchangeably. It would have been obvious to one of ordinary skill in the art to dip the device into a bath of a substance instead of spraying with the expectation of similar, successful results in achieving uniform, adherent coatings. As outlined below, regarding claim 14 Subramaniam also discloses flooding supercritical fluid into the coating chamber.

Regarding claims 5 and 6, the supercritical fluid of Subramaniam dissolves the therapeutic until, at a predetermined concentration, it is no longer a solvent for the medicament and the therapeutic agent precipitates. At this point, the dispersion agent is temporarily suspended therein.

The references fail to specifically teach recycling of the therapeutic agent. However, Examiner notes that the method of spraying or dipping a medical device into a solution/dispersion of therapeutic agent will not result in the attachment of all therapeutic agent present in the solution/dispersion. After coating, excess therapeutic

agent will remain. Due to the high expense of pharmaceutical products, it is Examiner's position that one of ordinary skill in the art would recycle the excess solutions/dispersions to recover the expensive pharmaceutical agents therein for a subsequent coating operation. In recovering the solution or dispersion from the coating chamber, a pump would be required to move the solution. Creating a pressure differential, using a vacuum would have been obvious to one of ordinary skill in the art desiring to move the solution from the chamber to a recycling location.

Regarding claim 10, Hossainy teaches the use of paclitaxel as the therapeutic agent (col. 7, line 60). Subramaniam teaches that the supercritical fluid may be carbon dioxide (examples and throughout).

Hossainy teaches coating stents (abstract), as required in claim 11.

Regarding claim 14, Subramaniam teaches pumping the supercritical fluid into a coating chamber containing the solution/dispersion of therapeutic agent until the solvent is displaced by a predetermined concentration of supercritical fluid and the therapeutic precipitates (col. 7, lines 35-45). Therefore, the supercritical fluid begins to interface with the therapeutic prior to the entire coating chamber being flooded with supercritical fluid.

Regarding claim 15, the supercritical fluid inherently swells the polymer coating portion of the solution/dispersion. Because the method claim limitations of Applicant's are met by Hossainy in view of Subramaniam, the polymer carrier of Hossainy and Subramaniam must inherently be swelled by the supercritical carbon dioxide in the same manner as it does in Applicant's invention. If there is some difference between the swelling of Applicant's coating and that of Hossainy in view of Subramaniam's, it must be due to some process limitation not present in Applicant's claim.

Conclusion

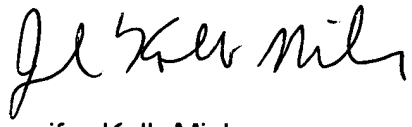
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Greiner is cited for teaching coating of polymeric medical devices by interfacing a therapeutic with supercritical fluid and transferring the therapeutic from the fluid to the medical device. Perman is cited for teaching coating a polymeric substrate by interfacing a therapeutic with supercritical fluid and transferring the therapeutic from the fluid to the medical device using a swellable carrier coating. Cook et al. is cited for teaching coating a metal stent with a polymer by interfacing the polymer with supercritical fluid and transferring the polymer from the fluid to the medical device. Albano is cited for teaching application of a drug and polymer by supercritical fluid. Mehta is cited for those reasons outlined in the previous office action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-

306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



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July 28, 2003